

***ETAILED ACTION***

1. Applicants' amendments of 07/26/2006 are acknowledged. Claims 3, 4, 5, 6, 7, 8, 11, 18, 19, 22 and 23 have been amended. Claims 13 and 21 have been canceled.

***Status of claims***

2. Claims 1-12, 14-20 and 22-23 are pending and under consideration.

***Sequence Requirements***

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821-1.825 for the reason(s) set forth below. Full compliance with the sequence rules is required in response to this office action. Drawings submitted 7/26/2006 include sequences which are identified as SEQ ID NO:1 and SEQ ID NO:2. However, no CRF or a separate sequence listing has been provided by the applicants.

***Drawings***

4. The drawings submitted 7/26/2006 have been accepted by the examiner.

***Specification***

5. The Abbreviations "sTREM-1" has been used in the specification. Full name of said abbreviation is required.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Information Disclosure Statement***

6. The information disclosure statement filed 7/26/2006 has been considered. An initialed copy is enclosed.

***Election/Restrictions***

7. Applicants' election with traverse of 6/29/2009 is acknowledged. The traversal is on the ground(s) that the search and examination of Groups I-III does not present an undue burden has been noted.

This is not found persuasive because while the searches may overlap but they are not coextensive. The requirement is still deemed proper and is therefore made FINAL.

Claims 12 and 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-11, 18, 19, 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite by using the abbreviation sTREM-1 without reciting what the full name of said term. Full name of said abbreviation is required when recited first time in the claim.

Claim 1 recites the limitation "the level" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**11.** Claims 1, 2, 3, 8, 10, 11, 18, 19, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Margolin et al. WO 02/058721 A1 (prior art of record).

The claims are drawn to a method of diagnosing disease of bacterial or fungal origin in a subject, which method comprises the step of measuring the level of sTREM-1 in a biological sample obtained from said subject.

Margolin et al. teach a method of diagnosing disease in a subject, which method comprises the step of measuring the level of sTREM-1 in a biological sample obtained from said subject ( see abstract, claims specially claims 26, 31, 32 and 36 and pages 19 and 20). Margolin et al. teach bacterial disease such as toxic shock, see page 44. Margolin et al. teach limitations of claims 18 and 19 see page 19. Margolin et al. teach

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immunochemical techniques (limitation of claims 22 and 23) see page 20. The prior art teaches the claimed method.

**12.** Claims 1-8, 10-11 18, 19, 20, 22 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Colona et al. US 2003/0165875A1

The claims are drawn to a method of diagnosing disease of bacterial or fungal origin in a subject, which method comprises the step of measuring the level of sTREM-1 in a biological sample obtained from said subject.

Colona et al. teach a method of diagnosing disease of bacterial or fungal origin in a subject, which method comprises the step of measuring the level of sTREM-1 in a biological sample obtained from said subject (see abstract and claims). Colona et al. teach TREM -1 receptor as a specific marker for bacterial and fungal sepsis (see abstract and page 26), immunochemical techniques (see page 27, paragraph 0247), anti bodies specific for TREM-1 ligand and receptor (see page 26 and paragraph 0246), and blood and plasma from human (see paragraph 0244). As to soluble form of TREM-1, it will inherent in TREM-1 taught by Colona et al. The prior art teaches the claimed method.

### ***Conclusion***

**13.** No claims are allowed.

**14.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S. Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on Mon, Wed 12:30-6:30 pm, Thur-Fri 12:30-4:30pm pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on (571)-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Khatol S Shahnan-Shah/  
Examiner, Art Unit 1645  
October 20, 2009

/Robert B Mondesi/  
Supervisory Patent Examiner, Art Unit 1645